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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/814,661	03/22/2001	Rodney Rothstein	56615-A-PCT-US/JPW/AJM/WW	2135

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EXAMINER	
UNGAR, SUSAN NMN	
ART UNIT	PAPER NUMBER
1642	10

DATE MAILED: 05/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/814,661	Rothstein et al
Examiner	**Art Unit**
Ungar	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *one* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 22, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-36* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

1. Claims 1-36 are pending in the application and are currently under prosecution.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at 703-308-3995. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group I. Claims 1-3 are drawn to a protein classified in Class 530, subclass 350.

Group II. Claims 4-10 are drawn to a DNA encoding a protein, a vector comprising said DNA, a host cell classified in Class 536, subclass 23.1 and Class 435, subclasses 320.1 and 326.

Group III. Claim 11 is drawn to an antisense nucleic acid molecule classified in Class 536, subclass 23.1.

Group IV. Claims 12 and 13 are drawn to an antibody classified in Class 530, subclass 387.1.

Group V. Claims 14-19 are drawn to a method for identifying compounds classified in Class 435, subclasses 4 and 6.

Group VI. Claims 20-23 are drawn to a compound classified in Class 530, subclasses 300+.

Group VII. Claim 24 is drawn to a method for inhibiting cell division *in vitro* classified in class 435, subclass 4.

Group VIII. Claims 25-28 are drawn to a method of inhibiting cell division *in vivo* classified in Class 514, subclass 2.

Group IX. Claims 29, and 31-36 are drawn to a method of treating cancer classified in Class 514, subclass 2.

Group X. Claims 30-36 are drawn to a method of treating microbial infection classified in Class 514, subclass 2.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV and VI as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions.

Inventions V and VII-X are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The inventions of Groups I and V/VII-X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with

another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the protein as claimed can be used in a materially different process such as affinity chromatography.

The inventions of Groups VI and V/VII-X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the compound as claimed can be used in a materially different process such as affinity chromatography.

The inventions of Groups II/ III/IV and V/VII-X are not at all related because the nucleic acid of Group II, the antisense nucleic acid of Group III and the antibody of Group IV are not used in any of the methods of Groups V/VII-X.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Group I is further subject to election of a single disclosed species.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising Sml1 proteins from different sources which would be expected to have at least different structures wherein the Sml1 proteins are (a) human Sml1 protein

(b) rat Sml1 protein, © mouse Sml1 protein, (d) microbial Sml1 protein, (e) plant Sml1, (g) insect Sml1 protein, all of claim 3.

6. Group II is further subject to election of a single disclosed species.

Claim 5 is generic to a plurality of disclosed patentably distinct species comprising nucleic acids encoding Sml1 proteins from different sources which have at different structures wherein the Sml1 proteins are (a) human Sml1 protein (b) rat Sml1 protein, © mouse Sml1 protein, (d) microbial Sml1 protein, (e) plant Sml1, (g) insect Sml1 protein. Claims 6-8 will be examined as they are drawn to the elected species.

7. Group II is further subject to election of a single disclosed species.

Claim 8 is generic to a plurality of disclosed patentably distinct species comprising vectors with different structures and mechanisms of action wherein the vectors are (a) a virus, (b) a plasmid, © a phage, (d) an expression vector, all of claim 9.

8. Group III is further subject to election of a single disclosed species.

Claim 11 is generic to a plurality of disclosed patentably distinct species comprising antisense sequences of nucleic acids encoding Sml1 proteins from different sources which have at different structures wherein the Sml1 proteins are (a) human Sml1 protein (b) rat Sml1 protein, © mouse Sml1 protein, (d) microbial Sml1 protein, (e) plant Sml1, (g) insect Sml1 protein.

9. Group IV is further subject to election of a single disclosed species.

Claim 12 is generic to a plurality of disclosed patentably distinct species comprising antibodies to Sml1 proteins from different sources which have at

different structures wherein the Sml1 proteins are (a) human Sml1 protein (b) rat Sml1 protein, © mouse Sml1 protein, (d) microbial Sml1 protein, (e) plant Sml1, (g) insect Sml1 protein.

10. Group IV is further subject to election of a single disclosed species.

Claim 12 is generic to a plurality of disclosed patentably distinct species comprising antibodies with different structures and functions, wherein the antibodies are (a) polyclonal (claim 13), (b) monoclonal (claim 14).

11. Group V is further subject to election of a single disclosed species.

Claim 14 is generic to a plurality of patentably distinct species comprising compounds with different structures or functions wherein the compounds are (a) an organic compound (claim 15), (b) a peptide (claim 15), © an inorganic compound (claim 15), (d) a lipid (claim 15), (e) a peptidomimetic (claims 15 and 16), (f) a small synthetic compound (claim 15).

12. Group V is further subject to election of a single disclosed species.

Claim 14 is generic to a plurality of patentably distinct species comprising cells with different origins, different structures and functions wherein the cells are (a) yeast (claim 18), (b) mammalian (claims 18 and 19), © plant (claim 18), (d) insect (claim 18), (e) microbe.

If species (b) is elected, species (b) is subject to election of a single disclosed species.

Claims 14 and 19 are generic to a plurality of patentably distinct species comprising mammalian cells with different sources which differ at least in structure

and function wherein the cells are (a) human, (b) hamster, © mouse, (d) rat, (e) monkey, all of claim 19.

13. Group VI is further subject to election of a single disclosed species.

Claims 20 and 21 are generic to a plurality of patentably distinct species comprising carriers with different structures wherein the carriers are (a) aerosol (claim 22), (b) topical aerosol (claim 22), © intravenous aerosol (claim 22), (d) oral aerosol (claim 22), (e) subcutaneous (claims 22 and 23).

14. Group VIII is further subject to election of a single disclosed species.

Claim 25 is generic to a plurality of patentably distinct species comprising treatments of diseases with different etiologies and mechanisms of action wherein the diseases are (a)increased cell division (claim 26), (b) microbial infection (claim 27), © ataxia telangiectasia (claim 28).

15. Group IX is further subject to election of a single disclosed species.

Claims 29 and 32 are generic to a plurality of patentably distinct species comprising carriers with different structures wherein the carriers are (a) aerosol (claim 33), (b) topical aerosol (claim 33), © intravenous aerosol (claim 33), (d) oral aerosol (claim 33), (e) subcutaneous (claims 33 and 34).

16. Group X is further subject to election of a single disclosed species.

Claims 30 and 32 are generic to a plurality of patentably distinct species comprising carriers with different structures wherein the carriers are (a) aerosol (claim 33), (b) topical aerosol (claim 33), © intravenous aerosol (claim 33), (d) oral aerosol (claim 33), (e) subcutaneous (claims 33 and 34).

17. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

18. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

20. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
May 6, 2002